EXHIBIT C

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	:	**CIVIL ACTION NO. 2:12-md-02327** ***MDL No. 2327***
This Document Applies To All Actions	:	Judge Joseph R. Goodwin

PLAINTIFFS' JOINT RESPONSES AND OBJECTIONS TO DEFENDANTS' FIRST SET OF REQUESTS FOR ADMISSIONS

Plaintiffs, by and through Plaintiffs' Co-Lead Counsel, hereby submit their Joint Responses and Objections to Defendants Ethicon, Inc. and Johnson & Johnson (collectively, "Defendants") First Set of Requests for Admissions to Plaintiffs.

GENERAL OBJECTION IN RESPONSE TO ALL REQUESTS

Defendants have served 138 requests for admissions upon each and every individual Plaintiff in the MDL 2327. As set forth below, the majority of these requests seek admissions relating to Defendants' own internal documents that they produced in this litigation – subject matters upon which the individual Plaintiffs in this MDL have no knowledge and no reason to have knowledge. Therefore, these requests seek information that has no bearing on this litigation. Clearly, Defendants have served the requests for admission on each and every individual Plaintiff in a strategic attempt to unduly burden and overwhelm Plaintiffs and their attorneys, which is improper and should not be permitted.

Pursuant to Pretrial Order No. 4 entered in MDL 2327, this Court noted that "Judge Stanley advised counsel of her expectations during the discovery process." Counsel were directed to "use the orders and protocols previously developed and entered in MDL 2187 *In re C.R. Bard, Inc., Pelvic Repair System Products Liability Litigation* when making proposals on

procedural and discovery issues in this MDL . . . . The court urged the parties to . . . devise proposed approaches to discovery which will accomplish discovery of the material facts in an efficient and economical manner." *Id.* at ¶ D.

In MDL 2187, *In re C.R. Bard, Inc., Pelvic Repair System Products Liability Litigation*, the Court entered Pretrial Order No. 8, which set forth, *inter alia*, its orders regarding selection of cases for individual discovery. *Id.* at ¶ 3. The Court ordered that the cases be divided into groups for individual discovery. *Id.* at ¶ 3(a). The Court then set forth the discovery to be completed in the initial pool of cases, including the exchange of Plaintiff and Defendant Fact Sheets. *Id.* at ¶ 3(b). The Court further ordered that the parties may serve up to two sets of Master Written Discovery for each product line and may serve case-specific written discovery in the cases selected for individual discovery. *Id.* at ¶ 5(c).

Pretrial Order No. 4 entered in MDL 2327 and Pretrial Order No. 8 entered in MDL 2187 make clear that Defendants are not permitted to serve written discovery on each and every individual Plaintiff in the MDL. Rather, aside from Master Written Discovery, service of written discovery is permissible only in the cases selected as the bellwether trial pool.

For these reasons, in addition to the reasons set forth below, Defendants' First Set of Requests for Admissions is improper, objectionable, and should not be permitted.

REQUESTS FOR ADMISSIONS

Notice of Claimed Investigational Exemption (IND #1688) - 1964

1. Admit that a genuine copy of Ethicon's Notice of Claimed Investigational Exemption for a New Drug for polypropylene sutures (IND #1688), dated March 25, 1964, is located at Bates numbered pages ETH.MESH.09625989 through 09626241.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

Prolene Suture New Drug Application (NDA #16-374) – 1966-1969

2. Admit that a genuine copy of Ethicon's initial New Drug Application for Prolene polypropylene monofilament sutures ("Prolene sutures") (NDA #16-374) dated January 17, 1966, is located at Bates numbered pages ETH.MESH.09625817 through 09625947, 09625962 through 09625973, and 09626242 through 09629458.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

3. Admit that the document attached as Exhibit 1 and produced at Bates numbered pages ETH.MESH.09625731 through 09625737 is a genuine copy of the FDA's approval letter dated April 16, 1969, for NDA #16-374, Prolene sutures.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of

admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

4. Admit that on April 16, 1969, the FDA approved Prolene sutures as "safe and effective for use as recommended in the submitted labeling."

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

5. Admit that the FDA approved the packaging, labels, and labeling submitted by Ethicon as part of NDA #16-374.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

Supplements to NDA #16-374 – 1970-1990

6. For each of the supplements to NDA #16-374 listed in Exhibit 2, admit that a genuine copy of Ethicon's application for the supplement (and any amendments to it) is located at the Bates numbered pages listed under the "Application" column.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

7. For each of the supplements to NDA #16-374 listed in Exhibit 2, admit that the applications were submitted to the FDA on or about the date(s) identified in Exhibit 2 under the "Application Date(s)" column.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

1970

8. Admit that the document attached as Exhibit 3 and produced at Bates numbered page ETH.MESH.09629720 is a genuine copy of the FDA's approval letter dated May 8, 1970, for Supplemental NDA #16-374/S-001.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

9. Admit that the FDA approved Supplemental NDA #16-374/S-001 on May 8, 1970.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

10. Admit that the document attached as Exhibit 4 and produced at Bates numbered page ETH.MESH.09629714 is a genuine copy of the FDA's amended approval letter dated June 29, 1970, for Supplemental NDA #16-374/S-001.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

11. Admit that the FDA amended its approval of Supplemental NDA #16-374/S-001 on June 29, 1970.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

1972

12. Admit that the document attached as Exhibit 5 and produced at Bates numbered page ETH.MESH.09630681 is a genuine copy of the FDA's approval letter dated August 17, 1972, for Supplemental NDA #16-374/S-002.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

13. Admit that the FDA approved Supplemental NDA #16-374/S-002 as amended on August 17, 1972.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of

admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

14. Admit that the document attached as Exhibit 6 and produced at Bates numbered page ETH.MESH. 09630683 is a genuine copy of the FDA's approval letter dated August 17, 1972, for Supplemental NDA #16-374/S-003.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

15. Admit that the FDA approved Supplemental NDA #16-374/S-003 on August 17, 1972.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

1973

16. Admit that the document attached as Exhibit 7 and produced at ETH.MESH.09630649 is a genuine copy of an April 26, 1973, letter from the FDA to Ethicon.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

17. Admit that in Exhibit 7 the FDA recommended the addition of the following language to the IFU: "[I]n order to furnish adequate information for the safe use of the drug: transitory local inflammatory reactions have been reported."

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

18. Admit that the document attached as Exhibit 8 and produced at Bates numbered page ETH.MESH. 09630640 is a genuine copy of the FDA's approval letter dated June 26, 1973, for Supplemental NDA #16-374/S-005.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of

admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

19. Admit that the FDA approved Supplemental NDA #16-374/S-005 as changed on June 26, 1973.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

20. Admit that the document attached as Exhibit 9 and produced at Bates numbered page ETH.MESH. 09630742 is a genuine copy of the FDA's approval letter dated September 10, 1973, for Supplemental NDA #16-374/S-004.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

21. Admit that the FDA approved Supplemental NDA #16-374/S-004 on September 10, 1973.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

1974

22. Admit that the document attached as Exhibit 10 and produced at Bates numbered page ETH.MESH. 09630944 is a genuine copy of the FDA's approval letter dated March 1, 1974, for Supplemental NDA #16-374/S-006.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

23. Admit that the FDA approved Supplemental NDA #16-374/S-006 on March 1, 1974.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than

Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

24. Admit that the document attached as Exhibit 11 and produced at Bates numbered page ETH.MESH. 09630985 is a genuine copy of the FDA's approval letter dated November 18, 1974, for Supplemental NDA #16-374/S-007.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

25. Admit that the FDA approved Supplemental NDA #16-374/S-007 on November 18, 1974.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

1975

26. Admit that the document attached as Exhibit 12 and produced at Bates numbered page ETH.MESH.09631401 is a genuine copy of the FDA's approval letter dated January 16, 1975, for Supplemental NDA #16-374/S-008.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

27. Admit that the FDA approved Supplemental NDA #16-374/S-008 on January 16, 1975.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

28. Admit that the document attached as Exhibit 13 and produced at Bates numbered page ETH.MESH.09631463 is a genuine copy of the FDA's approval letter dated June 4, 1975, for Supplemental NDA #16-374/S-010.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal

documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

29. Admit that the FDA approved Supplemental NDA #16-374/S-010 on June 4, 1975.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

30. Admit that the document attached as Exhibit 14 and produced at Bates numbered page ETH.MESH.09631174 is a genuine copy of the FDA's approval letter dated September 22, 1975, for Supplemental NDA #16-374/S-009.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

31. Admit that the FDA approved Supplemental NDA #16-374/S-009 as amended on September 22, 1975.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

1976

32. Admit that the document attached as Exhibit 15 and produced at Bates numbered page ETH.MESH.09631713 is a genuine copy of the FDA's approval letter dated October 22, 1976, for Supplemental NDA #16-374/S-011.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

33. Admit that the FDA approved Supplemental NDA #16-374/S-011 on October 22, 1976.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert

opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

1978

34. Admit that the document attached as Exhibit 16 and produced at Bates numbered page ETH.MESH.09632315 is a genuine copy of the FDA's approval letter dated May 12, 1978, for Supplemental NDA #16-374/S-014.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

35. Admit that the FDA approved Supplemental NDA #16-374/S-014 on May 12, 1978.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

36. Admit that the document attached as Exhibit 17 and produced at Bates numbered page ETH.MESH.09632331 is a genuine copy of the FDA's approval letter dated December 20, 1978, for Supplemental NDA #16-374/S-015.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

37. Admit that the FDA approved Supplemental NDA #16-374/S-015 on December 20, 1978.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

1979

38. Admit that the document attached as Exhibit 18 and produced at Bates numbered page ETH.MESH.09632606 is a genuine copy of the FDA's approval letter dated April 9, 1979, for Supplemental NDA #16-374/S-016.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know

whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

39. Admit that the FDA approved Supplemental NDA #16-374/S-016 as amended on April 9, 1979.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

40. Admit that the document attached as Exhibit 19 and produced at Bates numbered page ETH.MESH.09632774 is a genuine copy of the FDA's approval letter dated May 18, 1979, for Supplemental NDA #16-374/S-018.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

41. Admit that the FDA approved Supplemental NDA #16-374/S-018 on May 18, 1979.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

42. Admit that the document attached as Exhibit 20 and produced at Bates numbered page ETH.MESH.09632959 is a genuine copy of the FDA's approval letter dated December 6, 1979, for Supplemental NDA #16-374/S-019.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

43. Admit that the FDA approved Supplemental NDA #16-374/S-019 on December 6, 1979.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert

opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

1980

44. Admit that the document attached as Exhibit 21 and produced at Bates numbered page ETH.MESH.09632673 is a genuine copy of the FDA's approval letter dated January 4, 1980, for Supplemental NDA #16-374/S-017.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

45. Admit that the FDA approved Supplemental NDA #16-374/S-017 as amended on January 4, 1980.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

46. Admit that the document attached as Exhibit 22 and produced at Bates numbered page ETH.MESH.09632861 is a genuine copy of the FDA's approval letter dated April 23, 1980, for Supplemental NDA #16-374/S-012.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

47. Admit that the FDA approved Supplemental NDA #16-374/S-012 as amended on April 23, 1980.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

48. Admit that the document attached as Exhibit 23 and produced at Bates numbered page ETH.MESH.09632899 is a genuine copy of the FDA's approval letter dated April 23, 1980, for Supplemental NDA #16-374/S-013.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of

admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

49. Admit that the FDA approved Supplemental NDA #16-374/S-013 as amended on April 23, 1980.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

50. Admit that the document attached as Exhibit 24 and produced at Bates numbered page ETH.MESH.09632978 is a genuine copy of the FDA's approval letter dated May 2, 1980, for Supplemental NDA #16-374/S-020.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

51. Admit that the FDA approved Supplemental NDA #16-374/S-020 on May 2, 1980.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

52. Admit that the document attached as Exhibit 25 and produced at Bates numbered page ETH.MESH.09633026 is a genuine copy of the FDA's approval letter dated December 17, 1980, for Supplemental NDA #16-374/S-1.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

53. Admit that the FDA approved Supplemental NDA #16-374/S-1 on December 17, 1980.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

1981

54. Admit that the document attached as Exhibit 26 and produced at Bates numbered pages ETH.MESH.09633003 through 09633004 is a genuine copy of the FDA's approval letter dated January 6, 1981, for Supplemental NDA #16-374/S-021.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

55. Admit that the FDA approved Supplemental NDA #16-374/S-021 on January 6, 1981.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

56. Admit that the document attached as Exhibit 27 and produced at Bates numbered page ETH.MESH.09633211 is a genuine copy of the FDA's approval letter dated January 14, 1981, for Supplemental NDA #16-374/S-2.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of

admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

57. Admit that the FDA approved Supplemental NDA #16-374/S-2 on January 14, 1981.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

1983

58. Admit that the document attached as Exhibit 28 and produced at Bates numbered pages ETH.MESH.09633361 through 09633362 is a genuine copy of the FDA's approval letter dated April 7, 1983, for Supplemental NDA #16-374/S26.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

59. Admit that the FDA approved Supplemental NDA #16-374/S26 on April 7, 1983.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

1984

60. Admit that the document attached as Exhibit 29 and produced at Bates numbered pages ETH.MESH.09633425 through 09633426 is a genuine copy of the FDA's approval letter dated March 12, 1984, for Supplemental NDA #16-374/S27.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

61. Admit that the FDA approved Supplemental NDA #16-374/S27 on March 12, 1984.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert

opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

1985

62. Admit that the document attached as Exhibit 30 and produced at Bates numbered pages ETH.MESH.09633444 through 09633446 is a genuine copy of the FDA's approval letter dated June 10, 1985, for Supplemental NDA #16-374/S28.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

63. Admit that the FDA approved Supplemental NDA #16-374/S28 as amended on June 10, 1985.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

1986

64. Admit that the document attached as Exhibit 31 and produced at Bates numbered pages ETH.MESH.09633998 through 09634005 is a genuine copy of the FDA's approval letter dated January 23, 1986, for Supplemental NDA #16-374/S29.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

65. Admit that the FDA approved Supplemental NDA #16-374/S29 on January 23, 1986.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

66. Admit that the document attached as Exhibit 32 and produced as Bates numbered pages ETH.MESH.09634080 through ETH.MESH.09634081 is a genuine copy of Section 6 of Ethicon's Annual Experience Report for PROLENE polypropylene suture covering the period from April 16, 1985 through April 15, 1986.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of

admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

67. Admit that in 1986, Ethicon reported to the FDA that 1.58 million dozen sutures had been sold within the past 12 months, as stated in the document attached as Exhibit 32 and produced as ETH.MESH.09634081.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

68. Admit that the document attached as Exhibit 33 and produced at Bates numbered pages ETH.MESH.09634020 through 09634023 is a genuine copy of the FDA's approval letter dated May 23, 1986, for Supplemental NDA #16-374/S30.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

69. Admit that the FDA approved Supplemental NDA #16-374/S30 on May 23, 1986.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

70. Admit that the document attached as Exhibit 34 and produced at Bates numbered page ETH.MESH.09634106 is a genuine copy of the FDA's approval letter dated December 3, 1986, for Supplemental NDA #16-374/S31.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

71. Admit that the FDA approved Supplemental NDA #16-374/S31 on December 3, 1986.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert

opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

1987

72. Admit that the document attached as Exhibit 35 and produced at Bates numbered pages ETH.MESH.09634185 through 09634187 is a genuine copy of the FDA's approval letter dated August 28, 1987, for Supplemental NDA #16-374/S33.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

73. Admit that the FDA approved Supplemental NDA #16-374/S33 on August 28, 1987.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

1988

74. Admit that the document attached as Exhibit 36 and produced at Bates numbered pages ETH.MESH.09634299 through 09634303 is a genuine copy of the FDA's approval letter dated October 7, 1988, for Supplemental NDA #16-374/S34.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

75. Admit that the document attached as Exhibit 37 and produced at Bates numbered page ETH.MESH.09634318 is a genuine copy of proposed changes to the package insert for Prolene polypropylene sutures that Ethicon submitted to the FDA as part of NDA #16-374/S34.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

76. Admit that the proposed changes in NDA #16-374/S34 included labeling that warned of a "minimal, transient acute inflammatory reaction," and that it is not "subject to degradation or weakening by the action of tissue enzymes."

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

77. Admit that the proposed changes in NDA #16-374/S34 included labeling that said the material "resists involvement in infection."

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

78. Admit that the FDA approved Supplemental NDA #16-374/S34 on October 7, 1988.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

79. Admit that the document attached as Exhibit 38 and produced at Bates numbered pages ETH.MESH.09634354 through 09634356 is a genuine copy of the FDA's approval letter dated March 20, 1990, for Supplemental NDA #16-374/S35.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

80. Admit that the FDA approved Supplemental NDA #16-374/S35 on March 20, 1990.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

Prolene Suture Studies

81. Admit that the document produced at Bates numbered pages ETH.MESH.09626038 through 09626039 is a genuine copy of part of Ethicon's IND #1688, containing Usher, F.C., *Hernia Repair with Knitted Polypropylene Mesh*, Surgery, Gynecology & Obstetrics, Vol. 117, No. 2 (1963), submitted to the FDA as part of IND #1688.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

82. Admit that the document produced at Bates numbered page ETH.MESH.09629996 is a genuine copy of part of Ethicon's Fourth Quarterly Progress Report for NDA #16-374, containing an abstract of Morgan, J.E., *A Sling Operation Using Marlex Polypropylene Mesh for Treatment of Recurrent Stress Incontience*, Vol. 106, No. 3, pages 369–77 (1970), submitted to the FDA on April 24, 1970.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

83. Admit that the documents produced at Bates numbered pages ETH.MESH.09634276 and ETH.MESH.09634282 through 09634283 are a genuine copy of part of Ethicon's 1988 to 1989 periodic report for NDA #16-374, containing an abstract of Kersey, J. et al., *A Further Assessment of the Gauze Hammock Sling Operation in the Treatment of Stress*

Incontinence, British J. Obstet. Gynaecol., 95(4):382–385 (1988), submitted to the FDA on June 28, 1989.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

84. Admit that the document identified in Number 83 also contains an abstract of Gittes, R.F. & Foreman, R., *Transcutaneous Incorporation of Nonabsorbable Monofilament Sutures*, Surg. Gynecol.,Obstet., 166(6):545–548 (1988) submitted to the FDA on June 28, 1989.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

Reclassification Order

85. Admit that from 1969 until the passage of the 1976 Medical Device Amendments, the FDA regulated Prolene polypropylene monofilament sutures as a drug.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of

admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

86. Admit that, following the 1976 Medical Device Amendments enactment, the FDA regulated Prolene sutures as a Class III medical device.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

87. Admit that the document attached as Exhibit 39 and produced at Bates numbered pages ETH.MESH.09634664 through 09634688 is a genuine copy of a July 5, 1990, FDA order.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

88. Admit that according to Exhibit 39, the FDA reclassified nonabsorbable polypropylene surgical sutures from a Class III medical device to a Class II medical device with a low priority for the development of a performance standard.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

89. Admit that the document attached as Exhibit 40 and produced at Bates numbered pages ETH.MESH.09634662 through 09634663 is a genuine copy of a letter from the FDA to Ethicon dated October 12, 1990, regarding the FDA's decision to reclassify polypropylene sutures as a Class II medical device.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

90. Admit that on October 12, 1990, the FDA notified Ethicon that it reclassified PROLENE polypropylene sutures as a Class II medical device.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

510(k) Submissions

Modified PROLENE Mesh - 1996

91. Admit that a genuine copy of Ethicon's 510(k) Premarket Notification dated June 25, 1996, for Modified PROLENE polypropylene mesh nonabsorbable synthetic surgical mesh ("Modified PROLENE 510(k)") is located at Bates numbered pages ETH.MESH.05217103 through 05217144.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

92. Admit that a genuine copy of FDA's receipt letter to Ethicon concerning the Modified PROLENE 510(k) (K962530) is located at Bates numbered pages ETH.MESH.05217101 through 05217102.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

93. Admit that a genuine copy of Section I ("Modified Device and Description") of Ethicon's Modified PROLENE 510(k) is attached as Exhibit 41 and located at Bates numbered pages ETH.MESH.05217110 through 05217111.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

94. Admit that Ethicon's Modified PROLENE 510(k) states, in part, at ETH.MESH. 05217111 that "Modified PROLENE mesh is constructed of knitted filaments of extruded polypropylene identical in composition to that used in PROLENE* polypropylene suture nonabsorbable surgical sutures, U.S.P."

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than

Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

95. Admit that Ethicon's Modified PROLENE 510(k) states, in part, at ETH.MESH. 05217110 that the predicate device for Modified PROLENE mesh is "a preamendment device PROLENE polypropylene mesh nonabsorbable synthetic surgical mesh."

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

96. Admit that a genuine copy of the FDA's Clearance Letter for Ethicon's Modified PROLENE 510(k) dated August 9, 1996, is attached as Exhibit 42 and located at Bates numbered pages ETH.MESH.05217098 through 05217100.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

97. Admit that the FDA cleared Ethicon's 510(k) submission for Modified PROLENE on August 9, 1996.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

TVT - 1998

98. Admit that a genuine copy of Ethicon's 510(k) Premarket Notification dated October 29, 1997, for the Tension Free Vaginal Tape (TVT) System (K974098) ("TVT 510(k)") is located at Bates numbered pages ETH.MESH.08476210 through 08476342 and ETH.MESH.10040062 through 10040065.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

99. Admit that a genuine copy of Section I ("New Device and Description") of Ethicon's TVT 510(k) is attached as Exhibit 43 and located at Bates numbered pages ETH.MESH.08476243 through 08476245.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

100. Admit that the TVT 510(k) states that polypropylene mesh used in the Tension Free Vaginal Tape (TVT) System (K974098) "is the same Polypropylene mesh that is used to fabricate PROLENE polypropylene mesh," as stated in ETH.MESH.08476244.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

101. Admit that the TVT 510(k) states that polypropylene strands used to fabricate PROLENE mesh are the "same strands used to fabricate PROLENE Polypropylene Nonabsorbable Surgical Suture (NDA/PMA #16-374)," as stated in ETH.MESH.08476244.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than

Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

102. Admit that the PROLENE polypropylene mesh is the only part of the TVT System's device intended to be left in a patient's body following a TVT surgical procedure.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

103. Admit that a genuine copy of the FDA's Clearance Letter for Ethicon's TVT 510(k) dated January 28, 1998, is attached as Exhibit 44 and located at Bates numbered pages ETH.MESH.08476211 through 08476213.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

104. Admit that the FDA cleared Ethicon's 510(k) submission for TVT on January 28, 1998.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

105. Admit that FDA has never rescinded its clearance of the 510(k) premarket notification for the Tension Free Vaginal Tape (TVT) System (K974098).

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

106. Admit that FDA has never rescinded the 510(k) premarket notification for the Tension Free Vaginal Tape (TVT) System (K974098).

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

107. Admit that the FDA has never issued a Warning Letter to Ethicon, Inc. regarding the Tension Free Vaginal Tape (TVT) System (K974098).

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

108. Admit that the FDA has never issued a Warning Letter to Johnson & Johnson regarding the Tension Free Vaginal Tape (TVT) System (K974098).

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

TVT-AA/Blue - 2001

109. Admit that a genuine copy of Ethicon's 510(k) Premarket Notification dated August 9, 2001, for the Modified TVT-Blue System, with Accessory TVT-AA (K012628) ("Modified TVT-Blue 510(k)") is located at Bates numbered pages ETH.MESH.10039072 through 10039200.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of

admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

110. Admit that a genuine copy of Section I ("Modified Device and Description") of Ethicon's Modified TVT-Blue 510(k) is attached as Exhibit 45 and located at Bates numbered pages ETH.MESH.10039090 through 10039093.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

111. Admit that, according to the Modified TVT-Blue 510(k), the Modified TVT-Blue System, with Accessory TVT-AA (K012628) ("TVT Blue") "is a modification of the currently marketed TVT device and accessories covered under 510(k) (K974098) cleared January 28, 1998" as stated in ETH.MESH.10039090.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal

conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

112. Admit that, according to the Modified TVT-Blue 510(k), the TVT Blue "contains the same blue pigmented polypropylene monofilaments as the currently cleared PROLENE* soft Polypropylene Mesh K001122 cleared on May 23, 2000" as stated in ETH.MESH.10039090.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

113. Admit that, according to the Modified TVT-Blue 510(k), the TVT Blue is distinguished, in part, from the TVT system "by the inclusion of blue pigmented polypropylene fibers (approximately 50%) interwoven in the same manner as the current unpigmented TVT device," and that the "blue pigmented monofilaments are made from the same unpigmented polypropylene fibers colored with blue pigment [Phthalocyaninato(2-)] copper," as stated in ETH.MESH.10039090.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert

opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

114. Admit that, according to the Modified TVT-Blue 510(k), the TVT Blue "is a sterile single-use device that is composed of one piece of approximately 50% unpigmented and 50% pigmented blue [Phthalocyaninato(2-) copper], (Colour index Number 74160) polypropylene mesh," and that "this is the same Polypropylene Mesh that is used to fabricate PROLENE* Soft Polypropylene mesh (K001122) and PROLENE* Polypropylene Mesh (K962530)," as stated in ETH.MESH.10039092.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

115. Admit that, according to the Modified TVT-Blue 510(k), the "PROLENE mesh is fabricated from polypropylene strands of clear and clear/blue pigmented polypropylene fiber," and that "these same strands are used to fabricate PROLENE* Polypropylene Nonabsorbable Surgical Suture, undyed of blue pigment, (NDA;PMA #16-374) manufactured and marketed by ETHICON, Inc." as stated in ETH.MESH.10039092.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than

Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

116. Admit that a genuine copy of the FDA's Clearance Letter for Ethicon's Modified TVT-Blue 510(k) submission, dated October 26, 2001, is attached as Exhibit 46 and located at Bates numbered pages ETH.MESH.10039077 through 10039079.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

117. Admit that the FDA cleared Ethicon's 510(k) submission for the Modified TVT-Blue System on October 26, 2001.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

118. Admit that the PROLENE polypropylene mesh is the only part of the Modified TVT-Blue System intended to be left in a patient's body following a TVT surgical procedure.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

119. Admit that FDA has never rescinded its clearance of the Modified TVT Blue 510(k) (K012628).

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

120. Admit that FDA has never rescinded the Modified TVT Blue 510(k) (K012628).

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert

opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

121. Admit that the FDA has never issued a Warning Letter to Ethicon, Inc. regarding the TVT Blue device (K012628).

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

122. Admit that the FDA has never issued a Warning Letter to Johnson & Johnson regarding the TVT Blue device (K012628).

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

TVT-O - 2003

123. Admit that a genuine copy of Ethicon's 510(k) Premarket Notification dated December 8, 2003, for the GYNECARE TVT Obturator Device (K033568) ("TVT-O 510(k)") is located at Bates numbered pages ETH.MESH.07876926 through 07877006 and ETH.MESH.10039201 through 10039204.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

124. Admit that a genuine copy of Section I ("Modified Device and Description") of Ethicon's TVT-O 510(k) is attached as Exhibit 47 and located at Bates numbered pages ETH.MESH.07876943 through 07876945.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

125. Admit that, according to the TVT-O 510(k), the predicate device for the GYNECARE TVT Obturator Device "is a modification of the currently marketed GYNECARE TVT device covered under 510(k) K974098 cleared January 28, 1998" and "contains the same blue pigmented polypropylene monofilaments as the currently cleared TVT Blue with Abdominal Guides K012628 cleared on October 26, 2001," as stated in ETH.MESH.07876943.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

126. Admit that a genuine copy of the FDA's Clearance Letter for Ethicon's TVT-O 510(k) submission, dated December 8, 2003, is attached as Exhibit 48 and located at Bates numbered pages ETH.MESH.07876929 through 07876931.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

127. Admit that the FDA cleared Ethicon's TVT-O 510(k) submission on December 8, 2003.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert

opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

128. Admit that the PROLENE polypropylene mesh is the only part of the device intended to be left in a patient's body following a GYNECARE TVT Obturator surgical procedure.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

129. Admit that FDA has never rescinded its clearance of the 510(k) premarket notification for the GYNECARE TVT Obturator Device (K033568).

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

130. Admit that FDA has never rescinded the 510(k) premarket notification for the GYNECARE TVT Obturator Device (K033568).

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

131. Admit that the FDA has never issued a Warning Letter to Ethicon, Inc. regarding the GYNECARE TVT Obturator Device (K033568).

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

132. Admit that the FDA has never issued a Warning Letter to Johnson & Johnson regarding the GYNECARE TVT Obturator Device (K033568).

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

Updated Clearance - 2012

133. Admit that a genuine copy of the FDA's updated clearance letter for Ethicon's TVT 510(k) submission (K974098), dated September 28, 2012, is attached as Exhibit 49 and located at Bates numbered pages ETH.MESH. 10040062 through10040065.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

134. Admit that the FDA issued an updated clearance letter for the TVT System on September 28, 2012.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

135. Admit that a genuine copy of the FDA's updated clearance letter for Ethicon's Modified TVT-Blue 510(k) submission (K012628), dated September 28, 2012, is attached as Exhibit 50 and located at Bates numbered pages ETH.MESH. 10039072 through 10039074.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

136. Admit that the FDA issued an updated clearance letter for the TVT-Blue System on September 28, 2012.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

137. Admit that a genuine copy of the FDA's updated clearance letter for Ethicon's TVT-O 510(k) submission (K033568), dated September 28, 2012, is attached as Exhibit 51 and located at Bates numbered pages ETH.MESH. 10039201 through 10039204.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the document identified is one of Defendants' internal documents. Therefore, Defendants, rather than Plaintiffs, know or should know whether the copy

identified is genuine. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

138. Admit that the FDA issued an updated clearance letter for the TVT-O Device on September 28, 2012.

Answer: Plaintiffs object to the request on the grounds that it calls for speculation, is unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence in that the request seeks information that Defendants, rather than Plaintiffs, know or should know. Further objecting, this request calls for an expert opinion and/or a legal conclusion. Further objecting, this request seeks information protected by the attorney-client privilege and the work product doctrine.

PLAINTIFFS' CO-LEAD COUNSEL

Dated: December 2, 2013

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